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Omron Healthcare, Inc.
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Lake Forest, IL 60045 USA

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Official Contact: Mirna DiPano– Director, Quality & Regulatory

Proprietary or Trade Name: Model – HBP-1300

Common/Usual Name: Noninvasive blood pressure measurement system.

Classification Name/Code: DXN – Noninvasive blood pressure measurement system
21CFR 870.1130
Class II

Device: Model – HBP-1300

Predicate Device: Omron – HEM-907XL – K032305

Device Description:
The device is an automatic non-invasive blood pressure system. The device is battery powered and can also be powered from an IEC 60601-1 compliant AC adaptor. The device inflates a cuff with an integral pump then deflates the cuff via an electronically controllable valve. During deflation the cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic pressure.

The device is intended to be used with specified Omron cuffs in five sizes to encompass arms ranging from 5 to 20 inches in circumference.

The device also detects the appearance of irregular heartbeats during measurement.

Intended User
Model – HBP-1300 for prescriptive use by qualified medical personnel

Patient Population
This device is intended for use on adults and children of age 3-years and older.

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Indications for Use:
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult and pediatric (> 3 year old) patient population with arm circumference ranging from 5 inches to 20 inches (from 12 cm to 50 cm)

The device also detects the appearance of irregular heartbeats during measurement.

Environment of Use:
Model – HBP-1300 - Hospital, acute care settings, outpatient surgery, healthcare practitioner facilities

Contraindications
There are no known contraindications.

Summary of substantial equivalence
The HBP-1300 was compared to the predicate HEM-907XL (K032305) in the device comparison table below.

Device Comparison

	Omron HBP-1300	Omron HEM-907XL 510(k) K032305	Comment
Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult and pediatric (> 3 year old) patient population with arm circumference ranging from 5 inches to 20 inches (from 12cm to 50 cm) The device also detects the appearance of irregular heartbeats during measurement.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 7 inches to 20 inches (from 17 cm to 50 cm). The device also detects the appearance of irregular heartbeats during measurement.	Addition of smaller cuff and pediatric category as appropriate for cuff sizes supported.
Patient Population	Adult and pediatric (> 3 years old)	Adult	As above
Environment of Use	Rx - Hospital, acute care settings, outpatient surgery, healthcare practitioner facilities	OTC	Rx
Patient Connection	Yes via cuff	Yes via cuff	identical
Technology	Oscillometric	Oscillometric	identical
Measurement range	Pressure: 0-300 mmHg Pulse rate: 30 to 200 bpm	Pressure: 0-299 mmHg Pulse rate: 30 to 199 bpm	Similar
Accuracy or pressure indicator	+/- 3 mmHg	The higher of +/-3 mmHg or 2% of reading	HBP-1300 more accurate
Accuracy Pulse Rate	+/-5%	+/-5%	Identical
Inflation Method	DC rolling pump	DC rolling pump	Identical
Deflation Method	Dynamic linear deflation	Dynamic linear deflation	Identical
Display Type	LCD	LCD	Identical
Irregular pulse detection	Yes	Yes	Identical
Auscultatory	Yes	No – suggested to use stethoscope when irregular pulse is detected	Identical
Power Source	NiMH battery or AC adapter	NiMH battery or AC adapter	Identical
Operating Conditions	Temperature: 5° to 40 ° C Humidity: 15 to 85% RH	Temperature: 10 ° to 40 ° C Humidity: 30 to 85% RH	Similar

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Storage Conditions	Temperature: -20° to 60° C Humidity: 10 to 95% RH	Temperature: -25° to +70°C Humidity: 10 to 90% RH	Similar
Dimensions	123(W) x 201(D) x 99(H) mm	139(W) x 1310(D) x 203(H) mm	Slight smaller
Weight	1.3 lbs	1.98 lbs	Weighs less

Differences Between Other Legally Marketed Predicate Devices
The Omron HBP-1300 is viewed as substantially equivalent to the predicate device because: The HBP-1300 uses the exact same technology and has substantially equivalent indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications – The indications for use are substantially equivalent. The HBP-1300 is also indicated for use with pediatric (>3 year old) patients and has been shown accurate clinically.

Prescriptive – The HBP-1300 is for prescriptive use.

Design and Technology – The HBP-1300 has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The HBP-1300 has equivalent specifications of performance as the predicate.

Compliance with standards – The HBP-1300 and predicate device declare compliance with IEC 60601-1 and IEC 60601-1-2.

Materials – The patient contacting materials of the cuffs has been tested in accordance with ISO 10993-1 and FDA Guidance.

Environment of Use –
Model – HBP-1300 - Hospital, acute care settings, outpatient surgery, healthcare practitioner facilities

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Patient Population – The HBP-1300 is indicated for adult and pediatric populations, safety and effectiveness for the pediatric application has been demonstrated clinically and in accordance with the applicable FDA recognized consensus standard.

Performance Testing:
We have performed bench tests and found that the HBP-1300 met all requirements specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to IEC 60601-1
- Testing for compliance to IEC 60601-1-2
- Testing for compliance to IEC 80601-2-30
- Testing for compliance to AAMI SP10
- Comparative Testing to the Predicate

Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/ISO 81060-2. This testing was performed on 50 adults and 35 children with results showing compliance to the standard.

Conclusion
Omron maintains that the HBP-1300 is substantially equivalent to the predicate HEM-907XL (K032305) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 27 2012

Omron Healthcare, Inc.
c/o Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K113185
Trade/Device Name: HBP-1300
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: December 21, 2011
Received: December 22, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

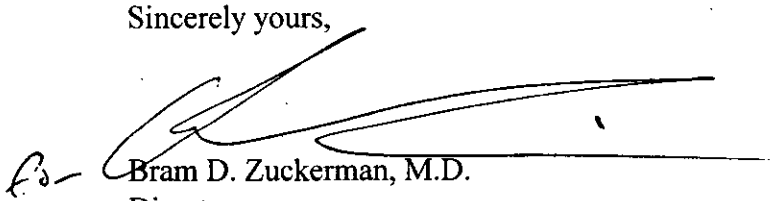
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K113185

Device Name: HBP-1300

Indications for Use:

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Model – HBP-1300 for prescriptive use by qualified medical personnel in hospitals, acute care settings, outpatient surgery, healthcare practitioner facilities

Prescription Use XX (Part 21 CFR 801 Subpart D) or **Over-the-counter use** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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